K081951

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AUG 15 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 24, 2008

1. Company and Correspondent making the submission:

Name	Wenzhou Kindcare Import & Export Co., Ltd.
Address	F407, Zhannan Commercial & Trading Bldg, Wenzhou, Zhejiang, China
Telephone	+86 -577-8676 7197
Fax	+86 577-8678 0748
Contact	Mr. Robin Miao / Manager
Email	Robin@Kindcare.Cn or Robin@Kindmed.Com

2. Device:

Trade/proprietary name:	Aneroid Sphygmomanometer Model KT-A01 with Stethoscope
Common Name:	Blood Pressure Cuff
Classification Name:	Blood Pressure Cuff

Substantial Equivalence was demonstrated by compliance to ANSI/AAMI SP10: 2002 & ANSI/AAMI SP10: 2002/A1: 2003, ISO 10993: 2003 Biological Evaluation of Medical Devices

3. Classifications Names & Citations:
21CFR 870.1120, DXQ, Blood Pressure Cuff, Class II

4. Description:

4.1 General

The Aneroid Sphygmomanometer Model KT-A01 with Stethoscope is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This Non-automated Sphygmomanometer uses an occluding cuff, an aneroid manometer to measure pressure, and a stethoscope for detecting Korotkoff sounds.

4.2 Direction

As discussed in the General description, the Wenzhou Kindcare Import & Export Co., Ltd., Aneroid Sphygmomanometer Model KT-A01 with Stethoscope is relatively simple to use. The attached stethoscope is placed on the inner arm above the bend in the elbow of the patient by detecting the pulse of the brachial artery. After inflation of the cuff, the user does auditory monitoring with the stethoscope to evaluate systolic and diastolic pressure. The two values are usually recorded as a ratio of the two measurements: systolic over diastolic.

4.3 The Aneroid Sphygmomanometer Model KT-A01 with Stethoscope contains:

1. Adjustable D-ring Cuff (Adult Size)
2. Stethoscope (Attaches to the cuff)
3. Non-stop rotary pin, 300 mmHg gauge
4. Instruction booklet and record
5. Carrying case

5. Indication for use:

Aneroid Sphygmomanometer Model KT-A01 with Stethoscope is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (noninvasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users at hospitals or at home to monitor both systolic and diastolic pressure. This device is sold with an adult D size cuff and suitable for use on adults.

5. Comparison with predicate device:

Wenzhou Kindcare import & Export Co., Ltd., believes that the Aneroid Sphygmomanometer Model KT-A01 with Stethoscope, is substantially equivalent to Wenzhou Longwan, Model AS101 BP Cuff. The devices have the same components, usage, patient population and functions. The packaging has the same claims, but varies only in the submitted device has more advertising verbiage regarding BP monitors.

7. Safety and Performance Data:
   Electrical, mechanical, environmental safety and performance testing according to standard AAMI SP10:2002. Specific testing relating to Aneroid Sphygmomanometer equipment was use to verify performance to recognized standards. All test results were satisfactory.

8. Conclusions:
   in accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Wenzhou Kindcare Import & Export Co., Ltd. concludes that the Aneroid Sphygmomanometer Model KT-A01 with Stethoscope is safe and effective and complies with the testing validations defined in AAMI /ANSI SP10 standard so that it is substantially equivalent to predicate devices as described herein.

9. Wenzhou Kindcare Import & Export Co., Ltd. will update and include in a summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Wenzhou Kindcare Import & Export Co., Ltd.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K081951
Trade/Device Name: Aneroid Sphygmomanometer Model KT-A01 with Stethoscope
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (Two)
Product Code: DXQ
Dated: July 28, 2008
Received: July 29, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081951

Device Name: Aneroid Sphygmomanometer Model KT-A01 with Stethoscope

Indications for Use:

Aneroid Sphygmomanometer Model KT-A01 with Stethoscope is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (noninvasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users at hospitals or at home to monitor both systolic and diastolic pressure. This device is sold with an adult D size cuff and suitable for use on adults.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use √ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081951